IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA *ex rel.* JEFFREY H. LIEBMAN and DAVID M. STERN, M.D.,	)	**Case No.: 3:17-cv-00902**
Plaintiff-Relators,	)	**District Judge William L. Campbell, Jr.**
v.	)	**Magistrate Judge Barbara D. Holmes**
METHODIST LE BONHEUR HEALTHCARE and METHODIST HEALTHCARE-MEMPHIS HOSPITALS,	)	
Defendants.	)	

METHODIST'S RESPONSE TO UNITED STATES' MOTION
TO EXCLUDE EVIDENCE RELATING TO PATIENT CARE AND OUTCOMES

Defendants Methodist Le Bonheur Healthcare and Methodist Healthcare-Memphis Hospitals (collectively, "Methodist") file this response in opposition to the United States' Motion to Exclude Undisclosed Evidence of Patient Care and Patient Outcomes. (Dkt. No. 308.)

PRELIMINARY STATEMENT

During discovery, Methodist served Requests for Admission asking the government to admit that it had not "identified any adverse impact on Methodist's patient outcomes due to the structure of the Affiliation Agreement" (RFA No. 3) or "any adverse patient outcomes that resulted from the co-management of any Methodist patients." (RFA No. 5). (Dkt. No. 271-6.) Because the government refused to admit or deny these RFAs (and refused to provide answers to numerous interrogatories or produce documents in response to numerous document requests), Methodist filed a series of discovery motions seeking to compel responses. (Dkt. Nos. 260, 271, 273.)

The discovery disputes were heard on December 20, 2022. At the hearing, the Court indicated that the government's responses to RFA Nos. 3 and 5 were insufficient but agreed to let

the parties brief whether the RFAs were relevant. (Dkt. No. 299.) The Court instructed Methodist to file motions to deem the RFAs admitted and warned the United States that, "I think you're going to have a hard row to convince me . . . that it's not relevant . . . But I will give you an opportunity to brief it as to relevancy. I'm simply cautioning you that I think there's going to be a very hard argument to make that this is not relevant in this case." (*Id.* at 81–82.)

On January 6, 2023, Methodist moved the Court to have RFA Nos. 3 and 5 deemed admitted. (Dkt. No. 301.) On January 13, 2023, the government filed an opposition to that motion and also filed the instant Motion to Exclude, requesting that the Court prevent Methodist from "presenting any evidence regarding patient care, the existence or non-existence of adverse patient outcomes, any purported benefit to patients and any other evidence relating to the impact on Methodist's patients resulting from Methodist's relationship with [West Clinic]." (Dkt. No. 308.)

On January 20, 2023, Judge Holmes granted Methodist's motion to deem RFA Nos. 3 and 5 admitted, concluding that the requests were relevant, and the government's responses were "unilateral, self-serving, and improper determinations by a party of its obligations under Rule 36." (Dkt. No. 312 at 9 n.4.)

The government's motion *in limine* should be denied for several reasons. First, the motion *in limine* is premature. Courts generally are reluctant to grant broad exclusions of evidence significantly in advance of trial because courts are better situated immediately prior to and during the actual trial to assess the value and utility of evidence. Filing this motion at the same time that it opposed Methodist's motion to deem RFAs admitted is a transparent attempt to challenge Judge Holmes' relevancy determination. But, if the government wanted to object to the Magistrate Judge's ruling, then it should have appealed that decision. Motions *in limine* are not intended to be an end-run around discovery rulings.

Second, the motion *in limine* should be denied because it is insufficiently specific. The motion identifies no concrete examples of testimony, documents, or evidence it seeks to exclude, but instead invites the Court to make broad categorical decisions on the exclusion of evidence. When the moving party fails to present specific evidentiary items to allow a court to assess relevancy or prejudice, courts routinely deny the motion *in limine* as merely an invitation to "rule in a factual vacuum."

Finally, the motion *in limine* should be denied because evidence related to improved patient care, outcomes, and benefits to Methodist's patients is not only relevant under Federal Rule of Evidence 401, but goes to the very heart of this case. The government alleges that the affiliation between Methodist and West to create a comprehensive cancer center was a fraud and a "sham," consisting of payments that were "disguised" as management fees but were actually kickbacks paid to West in exchange for referrals to Methodist. (*See* Dkt. No. 235 ("US Compl.").)[1] The government intends to point to West's failure to perform services as circumstantial evidence that Methodist must have been paying West for referrals instead of for work.

To establish willful misconduct under the Anti-Kickback Statute ("AKS"), the government will need to show that Methodist knew that its conduct was wrongful. Methodist contends that it

[1] Although the United States filed its Complaint less than a year ago, the "summary" of its case in the motions *in limine* contains almost no citations to its allegations and focuses on forms of alleged kickbacks (like assets acquired under the asset purchase agreement and professional services provided by nurse practitioners) that are not mentioned in the Complaint. (*See e.g.,* Dkt. No. 309 at 3.) As Judge Holmes recently explained, "[W]hen the United States intervened in this case, it was with the express representations and assurances to the Court that this would not become effectively a new lawsuit," but "those assurances have not been kept; that this has, in fact, morphed into a new lawsuit." (Dkt. No. 299 at 7–8.) The government cannot change the script post-production simply because it turns out there was no merit to the allegations in its pleadings. As explained in this brief, the substantial evidence Methodist has developed concerning the improvement of patient care under the parties' affiliation is directly responsive to the allegations contained in the Complaint and sworn interrogatory responses.

would be highly unlikely that it could know that the management services were not being performed (and hence know that any wrongful conduct was occurring) when the actual patient care, viewed against a wide body of objective benchmarks, showed substantially elevated cancer care for its patients. The evidence will show that the government's allegations regarding the lack of management services are disproven by numerous objective metrics such as Methodist's improved patient satisfaction scores, reduced hospital admissions following chemotherapy treatment, reduced cancer-related hospital readmissions, reduced cancer-related emergency department visits, reduced cancer-related admissions through the emergency department, increased patients screened for clinical trials, and increased patients receiving molecular testing for advanced lung cancer, and also by exceeding quality metrics for national accrediting bodies for medical oncology, gynecologic oncology, transplants, breast, lung, colon, ovarian, rectal, pancreatic, prostate, myeloma, head and neck, uterine, cervical, melanoma, and lymphoma cancers, and by providing substantial charity care so the broader community could also have access to these higher quality services.

This evidence tends to show that not only did Methodist have no reason to believe, contrary to the government's contention, that the base management services were not being provided, but that based on the significant work and outcomes achieved under West's management, stellar base management services were being provided. Further, Methodist, in light of these results, would have no reason to believe that West received excess payments for services as kickbacks, but would more likely have every reason to believe that West was actually being underpaid, as one witness has testified. In short, this evidence, far from being irrelevant, goes to the heart of Methodist's defense as to the elements of remuneration, scienter, and causation, which the government must prove to establish a violation of the AKS.

The government cannot claim that Methodist's payment of management fees were disguised kickbacks intended to induce patient referrals, but, at the same time, seek to prevent Methodist from putting on contrary evidence that the intent of the affiliation and the outcome of the affiliation were to improve cancer care. As set forth below, the evidence that the government seeks to exclude—none of which is specifically identified—would contradict the government's allegations and show that the government cannot satisfy its burden of proof on the essential elements of its case. The motion should be denied.

BACKGROUND

I. Complaint in Intervention

After originally deciding not to intervene in this *qui tam* lawsuit filed in 2017, on April 11, 2022, the United States filed a Complaint in Intervention seeking to recover "hundreds of millions of dollars in damages to Medicare as a result of Defendants' violations of the Anti-Kickback Statute ('AKS') and the [False Claims Act ('FCA')]." (US Compl. ¶ 1.)

The United States alleges that Methodist violated the AKS through its affiliation with the West Clinic to create the West Cancer Center. It alleges that the affiliation "purported to be a lawful way to allow West's patients to be treated at Methodist locations by West-employed physicians," and "[t]he stated goal was to create a comprehensive cancer center 'without walls' where patients in the mid-South could go for all their cancer-related care," (*see id.* ¶ 2), and to "make the Methodist inpatient facilities seamless with the outpatient sites to form a comprehensive cancer care center without walls. *In reality*, Methodist agreed to pay West in exchange for referrals." (*Id.* ¶ 196.) (emphasis added). So, the affiliation forming the West Cancer Center was nothing more than "a vehicle for kickbacks." (*Id.* at 38, § II (heading style omitted).)

In particular, the Complaint devotes more than 15 pages and 80 paragraphs to alleging that the Management Services / Performance Improvement Agreement ("MSA"), under which the West Clinic provided management services to improve the quality, efficiency, and effectiveness of Methodist's oncology service line, "cloaked Methodist's unlawful payments to West." (*Id.* at 39, § II(A) (heading style omitted).) In summarizing the kickback scheme, the Complaint alleges that "[k]ickbacks for the revenues Methodist generated from the West referrals, however, were disguised as payments Methodist made during the deal, and *expressly for certain services that were supposed to be—but were not—provided under the MSA*." (*Id.* ¶ 5) (emphasis added.)

The Complaint alleges that West did not provide management services at all the locations identified in the MSA, (*see id.* ¶¶ 207-25), and that West did not "perform[] a number of specific items identified in the MSA as base management and for which Methodist paid West." (*Id.* ¶ 226.) It alleges that "West kept no documentation for its services as the MSA required," (*id.* ¶¶ 245-58), and that "Methodist paid West monthly [management fees] without question," (*id.* ¶ 245), never once reviewing "any of the base management items in the MSA to confirm what West had performed during the seven years the MSA was in effect." (*Id.* ¶ 246.)

And, although the management fees Methodist paid to West were within fair-market value ranges set by third-party valuators, the Complaint alleges that the valuations were "in line with MSA terms, *but not with the parties' true intentions*," (*id.* ¶ 281) (emphasis added), because Methodist "never intended for West to provide base management services at all the locations in the MSA," (*id.* at 40 § II(A)(i) (heading style omitted).) Indeed, the Complaint alleges that "Methodist *knew* West did not provide all the services the MSA required, and that the assumptions underlying the FMV opinions were invalid, yet Methodist increased payments to West under the MSA as referrals increased." (*Id.* at 50 § II(A)(iv) (heading style omitted)) (emphasis added.)

Thus, according to the Complaint, the contracts were a "fiction" that the parties treated like "meaningless paper," which is "indicia of a sham agreement." (*Id.* ¶¶ 284, 286, 307.) The Complaint also alleges that Methodist saw increases in inpatient cancer revenue as a result of the partnership with West but this "should have been *viewed as a negative in terms of treatment outcomes*." (*Id.* ¶ 317) (emphasis added).

Methodist answered the Complaint by denying that it violated the AKS. (Dkt. No. 242.) Methodist is entitled to present evidence to rebut and disprove these false allegations.

II. Interrogatories

During discovery, Methodist served interrogatories asking the government to identify all of the "unlawful remuneration" it contends Methodist paid to the West Clinic. The government responded by claiming, among other things, that "[t]he amounts Methodist paid to West under the MSA also constituted remuneration," because "West kept no time records or specific documentation concerning the base management services, and Methodist asked for no support, there is no evidence to show exactly what West did . . . to comply with the MSA and for which Methodist paid West millions of dollars in base management fees." (*See* Dkt. No. 271-2 at 7.) The response claimed further that "despite the fact that West had not provided all of the management services in the MSA for 2012 and 2013 . . . in 2014 Methodist agreed to—and did—pay West $1 million more for the purported management services." (*Id*. at 7–8.)

III. Fact Discovery

During fact discovery, Methodist produced substantial evidence showing that, contrary to these allegations, the "true intentions" of the parties were in line with their "stated goal" of creating a comprehensive cancer center. Both deposition testimony and documents revealed that Methodist and West took the obligations of the contracts seriously, and that, in line with the express intent of

the MSA, they improved the quality, efficiency, and effectiveness of the oncology services provided at Methodist through valuable management services provided by the West physicians.

By way of example: Where the MSA provided that the West physicians would implement clinical protocols based on national best practice standards, (MSA, Ex. A ¶ 1.3), Methodist produced evidence showing that the West physicians devoted countless hours to creating, implementing, and tracking compliance with these care protocols, and, as a result, they were able to reduce (1) the number of patients requiring hospital admissions after receiving chemotherapy, (2) the number of cancer patients requiring re-admissions to Methodist's hospitals after discharge, (3) the number of emergency department visits by cancer patients, and (4) the number of cancer patients admitted to Methodist's hospitals through the emergency department. Where the MSA provided that the West physicians would assist in developing community awareness and education about the cancer center to community residents, (MSA, Ex. A ¶ 1.19), Methodist produced evidence showing that the West physicians invested substantial time in creating programs that resulted not only in education and awareness in the community, but also greatly increased screening and cancer detection in underserved areas, which, in turn reduced disparity gaps in treatment outcomes that had long plagued Memphis. Where the MSA provided that the West physicians were to coordinate the cancer service line in accordance with recognized standards to promote quality and efficient care, (MSA Ex. A ¶ 1.1), Methodist produced evidence showing that the West physicians created comprehensive treatment pathways for specific cancer types and formed multi-disciplinary conferences that brought together specialists in treating various aspects of those cancer types, which resulted in increased survival outcomes for breast, lung, uterine, and colon cancers that West tracked against national benchmarks and published in annual reports. It also resulted in increased patient satisfaction scores, and, by exceeding the quality criteria for

numerous national oncology organizations, it earned Methodist recognition, membership, accreditation, and certification with these organizations.[2]

ARGUMENT

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure authorize a court to rule on evidentiary motions *in limine*, but 'the practice has developed pursuant to the district court's inherent authority to manage the course of trials.'" *Thompson Rsch. Grp., LLC v. Winnebago Indus., Inc.,* 2021 WL 6750848, at *1 (M.D. Tenn. Feb. 11, 2021) (Campbell, J.) (quoting *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984)). The purpose of a motion *in limine* is to "narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions." *Louzon v. Ford Motor Co.*, 718 F.3d 556, 561 (6th Cir. 2013). "Unless a party proves that the evidence is clearly inadmissible on all potential grounds – a demanding requirement – 'evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.'" *Thompson Rsch. Grp.,* 2021 WL 6750848, at *1 (quoting *In re Davol*, 505 F. Supp. 3d 770, 774 (S.D. Ohio 2020)); *see also WEL Cos., Inc. v. Haldex Brake Prods. Corp*., 467 F. Supp. 3d 545, 555 (S.D. Ohio 2020) (reasoning because courts can better determine the "value and utility of evidence" during the trial, "[t]o obtain the exclusion of evidence

[2] These are offered merely as examples of the types of evidence Methodist has produced showing the West physicians' management and its effect on patient care and outcomes. As explained further below, the government carries the burden to identify the specific evidence it seeks to exclude. But, the government has failed to identify any specific evidence, and has instead broadly requested that all evidence relating to patient care, patient outcomes, intended benefits to patients, or actual benefits to patients be precluded. It does not fall to Methodist to track down and present the hundreds, if not thousands, of documents that have been produced or to mine the hours of testimony that has been offered showing that the parties' intent was to improve cancer care, and that, through the affiliation, they were successful. Indeed, it would be a tedious, if not impossible, task to parse the hundreds of thousands of pages of documents that have been produced and the dozens of hours of testimony that has been offered to even identify which aspects of that information would fall under the government's requested order *in limine*.

under such a motion, a party must prove that the evidence is clearly inadmissible on all potential grounds.").

I. The United States' Motion is Premature, Overbroad, and Insufficiently Specific.

"Courts 'are generally reluctant to grant broad exclusions of evidence before trial because a court is almost always better situated during the actual trial to assess the value and utility of evidence.'" *Thompson Rsch. Grp.*, 2021 WL 6750848, at *1 (quoting *In re Davol, Prod. Liab. Litig.*, 505 F.Supp.3d at 774); *see also Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) ("Orders *in limine* which exclude broad categories of evidence should rarely be employed. A better practice is to deal with questions of admissibility of evidence as they arise.")).

The government's broad request to categorically preclude Methodist from presenting any evidence regarding patient care, patient outcomes, and "any other evidence relating to the impact on Methodist's patients resulting from Methodist's relationship [with West]" is premature and extraordinarily overbroad.

The government's motion does not identify any specific documents, testimony, or evidence that it contends should be excluded, but instead requests a sweeping categorical decision that any evidence "regarding" patient care and outcomes or "relating to" the impact of the cancer center affiliation is irrelevant and should be precluded. "Where a motion *in limine* simply asserts objections without tying them to specific evidentiary items, the Court properly may deny it as overbroad and insufficiently specific." *Fakhoury v. O'Reilly*, 2022 WL 909347, at *6–7 (E.D. Mich. Mar. 28, 2022); *see also United States v. Frazier*, 443 F. Supp. 3d 885, 898 (M.D. Tenn. 2020) ("Even more fundamentally, the Government offers no specific concrete examples of any evidence it seeks to exclude. The Court will decline the Government's invitation to rule in a factual

vacuum."); *Jackson v. O'Reilly Auto. Stores, Inc.*, 131 F. Supp. 3d 756, 760 (M.D. Tenn. 2015) ("Here, we are unable to resolve Plaintiff's motion because he has not identified any particular piece of evidence that should be excluded. As a result, we cannot assess the likely relevancy or prejudice of the challenged evidence.")

The government's relevance arguments also fail more generally. "Unless a party proves that the evidence is clearly inadmissible on all potential grounds – a demanding requirement – 'evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.'" *Thompson Rsch. Grp.*, 2021 WL 6750848, at *1 (quoting *In re Davol, Prod. Liab. Litig.*, 2020 WL 7065764, at *2). As explained further below, evidence of improved patient care, better outcomes, and benefits to Methodist's patients and the community are all directly relevant to the claims and defenses in this action. At the very least, any decision regarding the admissibility of a particular piece of evidence should be decided at trial, not months before dispositive motions have even been filed.[3]

II. The Evidence the United States' Motion Seeks to Exclude is Relevant.

Rule 402 of the Federal Rules of Evidence provides "that evidence is admissible if it is 'relevant.'" *United States v. Miller,* 2022 WL 17464479, at *1 (E.D. Ky. Dec. 6, 2022) (quoting

[3] In a twist of logic, the United States represents that filing these motions *in limine* before discovery has closed or summary judgment has been briefed will somehow reduce "if not avoid" the strain on judicial resources of future motion practice. (*See* Dkt. No. 309 at 6 n.2.) Methodist disagrees. These motions exhibit the same "remarkable lack of regard for the Court's scarce judicial resources," for which the government has already been cautioned. (*See* Dkt. No. 258 at 2.) They are not only premature, but also appear to be a preemptive appeal of Judge Holmes' decision on the relevance of Methodist's requests for admission and a stab at getting a preview from the Court on legal issues likely to be briefed at summary judgment. Aspects of the government's motion are also completely unnecessary and could have been resolved by the parties had the United States done more than send one email on the topic to counsel for Methodist just days before filing. (*See* Dkt. No. 309-1.)

United States v. Dunn, 805 F.2d 1275, 1281 (6th Cir. 1986)). Rule 401 defines "relevant evidence" as evidence that "has any tendency to make a fact more or less probable than it would be without the evidence," and that "the fact is of consequence in determining the action." Fed. R. Evid. 401.

In this lawsuit, the United States alleges that Methodist's financial arrangements with West violated the AKS, which prohibits the **knowing and willful** payment of **remuneration** that is **intended to induce** referrals. *See* 42 U.S.C. § 1320a-7b(b) (emphasis added). A claim is false under the FCA only if it "includes items or services **resulting from** a violation [of the AKS]." *Id.* § 1320a-7b(g) (emphasis added). The evidence which the United States seeks to exclude is relevant to each of these elements of scienter, remuneration, and causation.

A. Remuneration

"An AKS violation [] requires that there be 'remuneration' offered or paid in the transaction at issue." *See Bingham v. HCA, Inc.*, 783 F. App'x 868, 873 (11th Cir. 2019). The Medicare Act broadly defines "remuneration" as "transfers of items or services for free *or for other than fair market value*," 42 U.S.C. § 1320a-7a(i)(6) (emphasis added). In the FCA context, appellate courts have pointed to this definition of remuneration, ruling that if a transaction is conducted at its fair market value (for example, if the West physicians were paid fair market value for their services), then the transaction does not breach the AKS. *Bingham*, 783 F. App'x at 873-75; *see also Miller v. Abbott Labs*, 648 F. App'x 555, 561 (6th Cir. 2016) (quoting statute); *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015) (same).

Methodist obtained fair-market value opinions for its payment of management fees approximately every two years during the affiliation with West, and its payments of management fees fell within a range approved by a valuator. The government alleges that the valuations were unreliable because they were "in line with MSA terms, *but not with the parties' true intentions*."

(US Compl. ¶ 281) (emphasis added). It also alleges that West kept "no documentation" of its management services, and neither Methodist nor any auditor ever requested or reviewed documentation to see if West was performing under the contract. (*See id.* ¶ 256.)

The government asserts that "Methodist has not disclosed evidence of patient care or patient outcomes, including any patient records, in its Initial Disclosures or in response to any discovery requests in this action. (Dkt. No. 309 at 1.) Either the government *still* has not reviewed Methodist's document productions, or the government is somehow remaining willfully ignorant of the contents of those productions, or, worse yet, the government is misrepresenting the contents of the productions. Evidence showing that, for example, West's management resulted in reduced hospital admissions and emergency room visits, increased early detection in the community, and increased survival rates for common cancer types speaks directly to the "value" of the management services the West physicians were providing and is relevant in determining whether the management fees were fair-market value for those services, in which case, they could not be unlawful "remuneration" under the AKS. *See Bingham*, 783 F. App'x at 873-75. That the United States does not ascribe value to improving cancer care does not mean that Methodist, valuators, the Court, or a reasonable jury will not ascribe value to that evidence.[4]

The government also argues that evidence of improved patient outcomes is irrelevant because "[t]he United States' allegations of unlawful remuneration are not based solely on payments Methodist made for services West failed to perform under the MSA." (Dkt. No. 309 at

[4] Neither the United States' Department of Health and Human Services, nor the Centers for Medicare and Medicaid Services, nor any other agency has defined "fair market value," and the government has admitted in this case that it has not identified any rules, regulations, guidance, official publications, provider education materials, or reports forbidding the methodologies used by the valuators Methodist engaged or the payment of management fees without timesheets or similar documentation. (*See* Dkt. No. 312 at 5, 10.)

9.) Although difficult to follow, the government appears to argue that because it has alleged multiple forms of remuneration, evidence from Methodist disproving only one form of remuneration is "irrelevant" unless that evidence disproves *all* alleged forms. In other words, if a fact is not dispositive of the entire case, then it is not relevant. That is flawed logic. If the government intends to allege multiple forms of improper kickbacks, then Methodist is entitled to put on evidence as to each alleged form of kickback. As this Court has explained, "[t]he standard for relevancy is extremely liberal. Even if a district court believes the evidence is insufficient to prove the ultimate point for which it is offered, it may not exclude the evidence if it has the slightest probative worth." *United States v. Oakes*, 2018 WL 4051869, at *1 (M.D. Tenn. Aug. 24, 2018) (cleaned up); *see also United States v. Lang,* 717 F. App'x 523, 530 (6th Cir. 2017) ("This threshold is low, and evidence is relevant if it 'advances the ball' one inch.")

B. Inducement

The United States must prove that any remuneration paid by Methodist to West was intended "to induce" referrals. 42 U.S.C. § 1320a-7b(b)(2)(A). The government argues that if, at summary judgment, the Court were to apply the judicially-created "one purpose rule," which has not been expressly adopted by the Sixth Circuit, then the government would only need to prove that one purpose of the remuneration was to induce patient referrals from West in order to satisfy this "inducement" element. (Dkt. No. 309 at 8.)[5] Going further, the government argues that if the

[5] The timing of the United States' motion, along with its inclusion of arguments on the application of the one-purpose rule, makes clear that its intent is not to protect against evidence that might mislead the jury, but rather to gain a preview of the Court's decisions on legal issues likely to be raised on summary judgment. Indeed, it asks the Court to preclude Methodist from presenting this evidence, not only at trial, but also at summary judgment. (*See* Dkt. No. 309.) The Court is more than capable of determining the relevance of evidence to the claims and defenses at issue at summary judgment—where it will determine if there are any genuine disputes of *material* fact. Indeed, Rule 56 provides a mechanism for objecting to evidence cited in support of, or to dispute, a fact at summary judgment. Fed. R. Civ. P. 56(c)(2). The United States' motions *in limine*

Court were to adopt its legal view, then evidence of any other legitimate bases for the management fees is irrelevant because "even if there was some benefit to patient[s] from Methodist's arrangement with West or if West actually performed services for Methodist, that does not mean there was no AKS violation. The United States only needs to show that Methodist also paid West in exchange for referrals in violation of the AKS." (*Id.* at 9.)

This too is flawed logic. First, the United States is inappropriately asking the Court to make a preliminary legal determination about application of the so-called one-purpose rule before the parties have completed discovery and submitted summary judgment motions. *See Louzon v. Ford Motor Co.*, 718 F.3d 556, 562-63 (6th Cir. 2013) (reversing an order *in limine* because the motion required the district court to engage in "summary-judgment analysis," remarking that "if these tactics were sufficient, a litigant could raise any matter *in limine*, as long as he included the duplicative argument that the evidence relating to the matter at issue is irrelevant").

Second, the government's argument presumes that it will be able to show that Methodist paid West not only for management services and better quality care, but also for West's patient referrals. This amounts to a request that the Court weigh the evidence (that the United States has not even identified) and find that no reasonable jury could conclude that the management fees were paid only for the management services and their resulting improvements. *Cf. Rosado-Martines v. Jackson*, 2017 WL 2544189, at *2 (W.D. Mich. June 13, 2017) ("Defendants are effectively asking the Court to weigh the evidence and make a finding…. A motion in limine is not the proper means to seek this relief.")[6]

seeking the broad preclusion of certain categories of fact from being relied on at summary judgment is, thus, not only improper, but an enormous waste of time and resources.

[6] In confounding fashion, the United States also argues that Methodist *could* defend the case if it were able to prove that patients "would have received inadequate care" absent the affiliation, and also "show that its arrangement with West improved cancer care." (Dkt. No. 309 at 6–7.) Setting

C. Scienter

The government must prove that Methodist "knowingly" and "willfully" acted in violation of the AKS, which requires a showing that Methodist "specifically intend[ed] to do something the law forbids, purposely intending to violate the law." *United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000).

In a recent AKS case, the Northern District of Georgia articulated how the government had failed to satisfy this element by presenting "scant evidence of Defendants' willfulness." *United States v. Holland*, No. 1:17-cr-0234 (N.D. Ga. Nov. 17, 2022) (previously filed at Dkt. No. 301-1). As in the instant case, the government alleged that a hospital disguised kickbacks through "sham" management contracts with a local clinic to provide services that the government claimed were "not needed, not justifiable, duplicative, substandard or problematic, and/or not rendered at all." (*Id*. at 3–4.) The *Holland* court concluded, however, that "Defendants are also entirely correct in arguing that, while the Government repeatedly states that the contracts between [the hospital] and [the clinic] were pretextual, they have not presented any evidence to support that assertion *or that Defendants believed the contracts were not legitimate.*" (*Id.* at 32.) (emphasis added). In particular, the *Holland* court determined that "[w]hile the Government may legitimately allege that it appears that one purpose of the contractual relationship between [the hospital] and [the clinic] was the referral of patients, *it is also apparent that the services provided by [the clinic] were valuable to [the hospital] and to the patients.*" (*Id*.) (emphasis added).

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aside the fact that the government seems to be creating new affirmative defenses and assigning new burdens of proof on the fly, it also invites the Court to conclude—without having reviewed any of the evidence—that "[t]here is not such evidence in the case." (*Id.*) Then, presuming the Court has accepted this characterization whole-cloth, the government asks the Court to preclude Methodist from introducing the very evidence it just claimed does not exist. (*Id.*)

Here, the government alleges the agreements between Methodist and West were "sham" contracts put on "meaningless paper" to "disguise the fraudulent relationship." (US Compl. ¶¶ 284, 286, 307) The government also alleges that Methodist knew the contracts were "a fiction" but that it "had no qualms about exactly how much it was paying West and for what services because Methodist was realizing all the gains in revenues from the outpatient and inpatient referrals." (*Id.* ¶ 327) The government has failed to develop proof supporting these allegations, so, instead, it is asking the Court to preclude Methodist from offering the overwhelming volume of evidence produced in discovery showing that the affiliation resulted in improved patient care, outcomes, and benefits to Methodist's patients—because that evidence would tend to show that the contracts were legitimate and that Methodist had good reason to believe they were legitimate. As the court explained in *Holland*, this evidence is not only relevant, but highly persuasive.

D. Causation

"A claim that includes items or services *resulting from* a violation [of the AKS] constitutes a false or fraudulent claim for purposes of the [FCA]." *See* 42 U.S.C. § 1320a-7b(g) (emphasis added). As the Eighth Circuit recently explained, this "resulting from" language requires the government to prove that "the harm would not have occurred in the absence of—that is, *but for*—the defendant's conduct." *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834-35 (8th Cir. 2022) (*quoting Burrage v. United States*, 571 U.S. 204, 211 (2014)) (internal quotation omitted). As applied here, the government has "to prove … that the defendants would not have included particular 'items or services' absent the illegal kickbacks." *Id.* at 835 (citations omitted).

The United States deposed three West physicians during discovery. Each physician testified that their decisions to refer patients and order services from Methodist did not result from payments made by Methodist. To the contrary, they testified that where they referred patients depended on

where they believed the patient would receive the best care, which typically was at Methodist since the physicians were managing a comprehensive cancer center there.

Evidence showing that, as a result of the affiliation, the quality of patient care at Methodist improved supports those doctors' testimony that they decided to send patients to Methodist not because of payments from Methodist but through their informed medical judgment. It is perhaps not surprising, albeit improper, that the government seeks to exclude evidence related to patient care that disproves its allegations of fraud. It is extremely surprising and disappointing, however, that the government would represent to the Court that no "evidence of patient care or patient outcomes" has been produced during discovery.

In sum, evidence of improved quality and outcomes for Methodist's patients would tend to show that Methodist did not pay any unlawful remuneration, nor did it intend for its payments to be for anything more than the services West provided; it had good reason to believe the management fees were legitimate and fair-market value; and the West physicians referred patients based on their medical judgment. It is no surprise that the government does not want this evidence introduced, but there is simply no basis to exclude it.

III. The Relevant Evidence Will Not Confuse the Court or a Jury.

Under Rule 403 of the Federal Rules of Evidence, courts "may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury[.]" Fed. R. Evid. 403. This balancing "test is strongly weighted toward admission." *United States v. Asher*, 910 F.3d 854, 860 (6th Cir. 2018); *see also United States v. Florence*, 2021 WL 5567001, at *1-2 (M.D. Tenn. Nov. 29, 2021) (quoting *Asher* and declining to exclude evidence before trial). Courts consider the challenged evidence in the light

most favorable to its proponent and only exclude evidence under Rule 403 that suggests a decision "on an improper basis." *United States v. Poulsen*, 655 F.3d 492, 509 (6th Cir. 2011).

The government reveals the true intent of its motion in arguing that if Methodist introduces evidence that its affiliation with West was "intended to improve cancer care," and also "that there was some benefit to cancer patients or that there was no harm done to patients" from the affiliation, such evidence "would confuse and mislead the jury into believing that because cancer care was improved Methodist should not be liable." (Dkt. No. 309 at 10.) Such evidence would neither "confuse" nor "mislead" the jury into concluding that Methodist is not liable. As explained above, evidence showing Methodist's intent and the results of the cancer center reveals that Methodist did not pay West unlawful remuneration, that Methodist did not knowingly and willfully violate the AKS, and that no patient referrals were sent from West to Methodist as a result of any alleged kickbacks. Based on this evidence, a jury would therefore *properly* conclude that Methodist is not liable for the "hundreds of millions of dollars" the government seeks to recover.

IV. The Government's Concern of "Undisclosed" Evidence Is Unfounded.

Much of the government's motion to exclude evidence of patient care and outcomes stems from a bald claim that Methodist is intending to rely on "undisclosed" documents that were not produced during fact discovery. (*See* Dkt. No. 309 at 4.) To conclude that Methodist requires additional "undisclosed" documents to show that the affiliation resulted in improved patient care and patient outcomes, the government has apparently ignored the tens-of-thousands of documents and dozens of gigabites of claims data produced in this case.[7] To the extent the government has

[7] Indeed, to date, Methodist has produced more than 180,000 pages of documents to the government in response to its Civil Investigative Demand and responded to approximately 200 discovery requests from Relators covering every aspect of its affiliation with West and the allegations in this case.

concerns at trial that Methodist is attempting to rely on evidence that was not produced or disclosed, those issues are better addressed at trial in the context of that specific evidence. *See Thompson Rsch. Grp.*, 2021 WL 6750848, at *1 ("[A] court is almost always better situated during the actual trial to assess the value and utility of evidence."). A motion *in limine* is neither necessary nor useful in attempting to prevent a party from introducing at trial some unidentified, as-of-yet unproduced, hypothetical evidence.

CONCLUSION

For the reasons stated above, the Court should deny the United States' Motion to Exclude Undisclosed Evidence of Patient Care and Patient Outcomes. (Dkt. No. 308.) The motion is premature, overbroad, and insufficiently specific. Although the United States has not identified any evidence in particular that it contends should be precluded, substantial evidence showing that the allegedly-fraudulent cancer center affiliation actually resulted in improved care and outcomes for Methodist's patients is relevant not only to the government's allegations, but also to the government's failures of proof on numerous elements in its case in chief.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been served on the following counsel via the Court's CM/ECF email notification system on this the 27th day of January, 2023:

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